



## Acetaminophen Safety

### What is acetaminophen (APAP)?

Acetaminophen, also known as paracetamol and abbreviated as “APAP” for its chemical name, N-acetyl-p-aminophenol, is an active ingredient found in many over-the-counter and prescription medicines to help relieve pain and reduce fever.<sup>1</sup> Medicines containing acetaminophen are available in many forms, including drops, syrups, capsules, and tablets.

Acetaminophen can be found in more than 600 over-the-counter and prescription medicines,<sup>1</sup> such as:<sup>2</sup>

- Tylenol®
- Robitussin®
- Midol®
- Nyquil®/Dayquil®
- Excedrin®
- Sudafed®
- Theraflu®
- Vicodin®
- Percocet®

### Are there any risks with acetaminophen?

The use of products containing acetaminophen in high doses over a long period of time can cause severe liver injury, with reports of up to 63 percent of unintentional acetaminophen overdoses associated with the use of opioid-acetaminophen combination products.<sup>3,4</sup>

The FDA issued a statement in January 2014 recommending that health care professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 mg of acetaminophen per tablet, capsule or other dosage unit because of a risk of liver damage if taken in doses exceeding the maximum recommended dose. According to the FDA statement, cases of severe liver injury have been reported in patients who took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period, took two or more acetaminophen-containing products simultaneously, or combined alcohol with acetaminophen.<sup>5</sup>

### How much is too much acetaminophen?

Medical discussions about how much acetaminophen is too much are ongoing. Currently, the U. S. Food and Drug Administration recommends consumers use no more than 4 grams of acetaminophen per day from any medication source.<sup>1</sup>

Consumers who are currently taking a prescription medication containing acetaminophen should speak to their healthcare providers about alternative medications for their condition(s) to avoid the risk of unknowingly overusing acetaminophen through an over-the-counter product containing acetaminophen.<sup>1</sup>

### How can consumers safely take acetaminophen?

The FDA recommends the following to consumers on acetaminophen safety:<sup>1</sup>

- Read all the information given to you by your doctor and follow directions.

- Read the information on the OTC “Drug Facts” label or on the prescription label and follow directions.
- Be sure you understand the following:
  - the dose, which is how much acetaminophen you can take at one time
  - how many hours you must wait before taking another dose of acetaminophen
  - how many doses of acetaminophen you can take safely each day
  - when to stop taking acetaminophen and ask a doctor for help
- Never take more than directed, even if your pain or fever isn’t any better. Taking more acetaminophen than directed can put you at risk for liver damage.
- Never take more than one medicine that contains acetaminophen. Check the active ingredients of all your medicines to make sure you are taking no more than one medicine containing acetaminophen at a time.

### **How can consumers determine whether a medication contains acetaminophen?**

All medicines have ingredients listed on their labels. In OTC medicines, which can be purchased in a pharmacy without a prescription, acetaminophen would be listed under the active ingredients of the “Drug Facts” label. On prescription medicine containers, the label would say “acetaminophen” or “APAP.”<sup>1</sup>

### **Where can consumers find more information on acetaminophen?**

Patients can speak to a doctor, nurse, or pharmacist or visit the FDA website [www.fda.gov](http://www.fda.gov).

Other acetaminophen information can be found via the following resources online:

- [KnowYourDose.Org](http://www.knowyourdose.org) brought to you by the Acetaminophen Awareness Coalition
- [Acetaminophen Safety FAQ](#) brought to you by WebMD

---

<sup>1</sup> [FDA Consumer Health Information. “Don’t Double Up on Acetaminophen”](#), US Food & Drug Administration. January 2013. Accessed Jan. 23, 2015.

<sup>2</sup> KnowYourDose.org. Acetaminophen Awareness Coalition. [http://www.knowyourdose.org/sites/default/files/acetaminophen\\_report.pdf](http://www.knowyourdose.org/sites/default/files/acetaminophen_report.pdf)

<sup>3</sup> Larson et al. Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study. *Hepatology*. 2005; 42(6): 1364-1372.

<sup>4</sup> Michna, E, Duh, MS, Korves, C, Dahl, JL. Removal of opioid/acetaminophen combination prescription pain medications: assessing the evidence for hepatotoxicity and consequences of removal of these medications. *Pain Medicine*. 2010; 11: 369-378.

<sup>5</sup> [Acetaminophen Prescription Combination Drug Products with more than 325 mg: FDA Statement – Recommendation to Discontinue Prescribing and Dispensing](#). U.S. Food & Drug Administration. Accessed Jan. 16, 2014.